Porcine Versus Polypropylene Sling For Stress Urinary Incontinence - Results Of A 10 Year Randomised Control Study

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Declaration of interests – none


10 year RTC comparing:
Pelvicol™ (Bard Urology) - a natural, non-allergenic, flexible and strong biological matrix derived from porcine dermis
TVT™ (Ethicon Inc.) – a macroporous type 1 polypropylene synthetic mesh

142 patients randomised to Pelvicol™ (74) or TVT™ sling (68)
› 128 patients completed 3 year follow-up (90% response rate)
› 98 patients completed 10 year follow-up (69% response rate)

Outcome measures:
Primary:
Patient determined continence status
(Success = cured or >90% improved)
(Improved = ≥75 <90% improved)
(Failed = <75% improved)

Secondary:
Repeat continence surgery
Use of incontinence pads
Adverse events
Patient satisfaction

Patient determined continence status

3 Year Follow-Up
10 Year Follow-Up

Pelvicol™ TVT™ Pelvicol™ TVT™

N=68 N=60 N=51 N=47

Success (≥90%)
56 (82.4%) 53 (88.3%) 24 (47.2%) 29 (61.8%) p = 0.03

Improved (≥75 <90%)
7 (10.3%) 3 (5.0%) 9 (17.5%) 9 (19.1%)

Failed (<75%)
5 (7.3%) 4 (6.7%) 18 (35.3%) 9 (19.1%)

Secondary Outcomes

Pelvicol™ TVT™ Pelvicol™ TVT™

N=68 N=60 N=37 N=43

Intermittent self catheterisation
2 (2.9%) 2 (3.3%) 0 0

Difficulty voiding
4 (5.9%) 5 (8.3%) 2 (5.4%) 6 (13%)

Pelvic pain
1 (1.5%) 1 (1.7%) 3 (8.1%) 4 (9.3%)

Dyspareunia
0 2 (3.3%) 3 (8.1%) 3 (6.9%)

Patient satisfaction:
The majority of patients in both groups would have the operation repeated again if needed, 62% in the Pelvicol™ group and 77% in the TVT™ group. 62% in the Pelvicol™ group would recommend the operation to a friend and 72% in the TVT™ group.

Discussion:
- 2015 Cochrane review on synthetic mesh slings, concluded established effectiveness and a good safety profile, although highlighted lack of long-term data and data on allogenic material slings.
- Both cure rates declined at 10 years compared to 3 years: Pelvic 82% to 47%, TVT 88% to 62% (significantly greater reduction in the Pelvicol group).
- Our re-operation rate of 8.5% in TVT group comparable to other 10 year follow-up studies who reported 7.8%. Re-operation rate of 27.5% significantly higher in the Pelvicol group, suggests Porcine slings inferior in the longterm.